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14. ABSTRACT

We propose a randomized controlled clinical trial of 1,200 military service members who are at increased risk for suicide but not currently in behavioral health treatment for the purpose of determining if a brief intervention improves the initiation of treatment. Participants assigned to the treatment condition will be presented an individualized CB intervention. The CB intervention takes 45-60 minutes, is delivered by phone, and has been shown to promote treatment-seeking including in a preliminary study of OEF/OIF Veterans with elevated posttraumatic stress disorder (PTSD) symptoms. Participants will be assessed at baseline and at 1-month, 3-month, and 6-month follow-up. Analyses are based on logistic and mixed effect models.

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nothing listed

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INTRODUCTION TO SPECIFIC AIMS

Reducing suicide is a national priority and an urgent concern within the Department of Defense and the Department of Veterans Affairs. The passage of the Joshua Omvig Veterans Suicide Prevention Act highlights the importance that stakeholders place on developing and implementing a comprehensive program to reduce suicide among U.S. service members and Veterans. Rates of suicide among active duty service members have increased dramatically since 2005, and there is great concern that elevated risk will carry over following discharge from active service. ***The goal of this study is to improve initiation of behavioral health (i.e., mental health, substance use) treatment services among untreated, at-risk U.S. military service members.*** The goal to facilitate behavioral health treatment is consistent with recommendations provided in reports by the Department of Defense, U.S. Army, U.S. Surgeon General, and the Institute of Medicine.

We are conducting a randomized controlled clinical trial of 1,200 military service members who are at increased risk for suicide but not currently in behavioral health treatment for the purpose of determining if a brief intervention improves attitudes toward behavioral health treatment and initiation of treatment. Advertisements are used to recruit service members who report current suicidal ideation or a history of suicide attempt on standard screening items, suggesting they are at risk for suicide. Participants assigned to the treatment condition are presented an individualized cognitive-behavioral (CB) intervention. The CB intervention takes 45-60 minutes, is delivered by phone, and has been shown to promote treatment-seeking including in a preliminary study of OEF/OIF Veterans with elevated posttraumatic stress disorder (PTSD) symptoms. Participants are assessed at baseline and at 1-month, 3-month, 6-month, and 12-month follow-up. Analyses are based on logistic and mixed effect models. **Specific Aims are as follows**:

1) *Test the effectiveness of the intervention on attitudes toward behavioral health treatment among at-risk service members*.
   Hypothesis 1a: Participants receiving the CB intervention will have significant increases in positive attitudes about treatment at 1-month follow-up compared to controls.
   Hypothesis 1b: Participants receiving the CB intervention will have significant increases in the intention to initiate behavioral health treatment compared to controls.

2) *Test the effectiveness of the intervention on the initiation of and adherence to behavioral health treatment.*
   Hypothesis 2a: Participants receiving the CB intervention will be more likely to initiate behavioral health treatment than participants in control group during 6-month follow-up.
   Hypothesis 2b: Participants receiving the CB intervention will attend more behavioral health treatment sessions than participants in the control group over 6-month follow-up.

The brief (45-60 min), practical (delivered by phone), and promising nature of the CB intervention (favorable preliminary data in OEF/OIF Veterans with elevated PTSD symptoms) indicate its potential for wider implementation to reduce suicide risk among service members.

ACCOMPLISHMENTS

Recruitment for this trial began on March 2, 2013. We aimed to recruit approximately 250 individuals during each year of the trial, and have 496 participants as of February 20, 2015, indicating that we are right on schedule. Of the 496 active participants, 404 of them are separated from the service, 73 are active in the National Guard or Reserves, and 19 are Active Duty.

Recruitment is ongoing and on track.

Baseline characteristics.
Characteristics of the participant sample that have been entered into the data management system are presented in Table 1. The mean age of participants is approximately 30 years old, and 90% of the sample is male. The majority of participants identify their race as white, non-Hispanic. The vast majority reported service in the Army. Baseline symptom severity scores indicate that both the intervention and control groups reported moderately severe symptoms of depression (mean score = 18) as measured by the PHQ9 and PTSD (mean score = 62) as measured by the PCL.

Twenty-four percent of the sample reported a previous suicide attempt during the baseline assessment. The majority of the attempts involved the use of medications. Overdosing on medications is also the most frequently reported method when asked if they have a plan for suicide. Other reported methods involve guns, cutting, car accidents, and carbon monoxide poisoning.

We have had three participants die during the trial. One participant died from heart failure related to the use of fentanyl, and two died as a result of overdosing on pain medications. One of these overdoses was categorized as a suicide. All of these outcomes were reported to all IRB's involved and were judged to be unrelated to study participation.

No SAE's have occurred during this trial period.

Modifications to protocol.
Three measures have been added to the assessment battery in order to improve the characterization of suicidal risk. These measures include the Insomnia Severity Scale to assess sleep, the Brief Pain Inventory to assess pain, and the Interpersonal Needs Questionnaire to assess the respondent's perception of feeling like a burden or thwarted belonging. Additionally, we have added a follow-up interview to occur at the 12-month point in order to better assess outcomes longitudinally.

REPORTABLE OUTCOMES

No reportable outcomes are available for this trial at this time.

Table 1: Baseline characteristics of the sample

Characteristic	Intervention Participants (*n* = 244)		Control Participants (*n* = 242)	
	n	%	*n*	%
Male	218	89.3	218	90.1
Female	26	10.7	24	9.9
Ethnicity				
White, non-Hispanic	166	68	153	63.2
White, Hispanic	18	7.4	25	10.3
Black, non-Hispanic	29	11.9	28	11.6
Black, Hispanic	3	1.2	1	.4
Native American	3	1.2	5	2.1
Asian/Pacific Islander	6	2.5	6	2.5
Other/or mixed race/ethnicity	17	7	21	8.7
Missing	2	.8	3	1.2
Branch of Service				
Army	170	69.7	166	68.6
Navy	18	7.4	21	8.7
Airforce	6	6.6	16	6.6
Marine	37	15.3	37	15.3
Coast Guard	0	0	0	0
Refused	1	.4	0	0
Missing	2	.8	2	.8
	Mean	Range	Mean	Range
Age	31.39	21-56	30.05	22-54
PHQ-9 score *at Baseline*	18.06	7-27	18.56	5-27
PCL score *at Baseline*	62.45	18-85	62.44	25-85

Table 2: Treatment at 1 month follow-up

Characteristic	Intervention Participants (*n* = 244)		Control Participants (*n* = 242)	
	n	%	*n*	%
Attended treatment	33	13.5	17	7.0
Number of sessions attended	Mean	Range	Mean	Range
	2.8	0-15	1.82	0-6